DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 12, 2015

Kossan International Sdn. Bhd.
Ms. Cho Sow Fong
Manager Regulatory Affairs
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Off Batu 3 ¾, Jalan Kapar
Klang, Selangor Darul Ehsan
MALAYSIA 42100

Re: K143131
Trade/Device Name: Powder Free Nitrile Patient Examination Glove, Black Colored, Non-Sterile.
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: January 6, 2015
Received: January 8, 2015

Dear Ms. Fong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143131

Device Name

Powder Free Nitrile Patient Examination Glove, Black Colored, Non-Sterile

Indications for Use *(Describe)*

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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FDA 510(k), Premarket Notification: 510(k) Summary of Safety and Effectiveness Information

Date Prepared: February 10, 2015

1.0 Submitter:

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2.0 Contact Person:

Contact: Ms Cho Sow Fong
Telephone No.: +603 3291 0516
Fax No.: +603 3291 0542

3.0 Name of Device:

Trade Name(s)	:	Powder Free Nitrile Patient Examination Glove, Black Colored, Non-Sterile.
Common Name	:	Powder-Free Nitrile Patient Examination Glove
Classification Name	:	Patient Examination Glove
Regulation Number	:	21 CFR 880.6250
Classification Number:		Class I
Product Code	:	80 LZA

4.0 Identification of the Legally Marketed Device:

Powder Free Nitrile Patient Examination Glove, Black Colored, Non-Sterile, Class I Patient Examination Gloves, Nitrile – 80 LZA, meets all of the requirements of ASTM D 6319-10 Standard Specification for Nitrile Examination Gloves for Medical Application.

Predicate Device 1: K121529, Black Powder Free Nitrile Patient Exam Glove.

There are no different technological characteristics compared to the Predicate Devices.

5.0 Description of Device:

Powder Free Nitrile Patient Examination Glove, Black Colored, Non-Sterile is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

The gloves are powder free, ambidextrous with beaded-cuff, black colored, single-use disposable devices that come in six sizes (XS, S, M, L, XL, XXL), and supplied in Non-Sterile state.

The gloves are made of Nitrile Butadiene Rubber, designed and manufactured in accordance with ASTM D6319-10, Standard Specification for Nitrile Examination Gloves for Medical Application.

Its physical and performance characteristics meet all requirements of ASTM D6319-10.

6.0 Indications for Use:

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

7.0 Summary of the Technological Characteristics of the Device:

Powder Free Nitrile Patient Examination Glove, Black Colored, Non-Sterile processes the following technological characteristic (as compared to ASTM or equivalent standards):

Characteristic	Standards Requirements	Results Summary			Conclusions
Dimensions	ASTM D6319-10	Length		≥ 230mm	Meets Standard Requirements
		Palm Thickness		≥ 0.05mm	
		Finger Thickness		≥ 0.05mm	
		Width	X-Small	70-80mm	
			Small	80-90mm	
			Medium	90-100mm	
			Large	101-111mm	
			X-Large	111-121mm	
			XX-Large	121-131mm	
Physical Properties	ASTM D6319-10		Before Aging	After Aging	Meets Standard Requirements
		Tensile Strength	≥ 14 MPA	≥ 14 MPA	
		Elongation	≥ 500%	≥ 400%	
Freedom from pinholes	ASTM D5151-11 ASTM D6319-10	Tested in accordance with ASTM D5151 test method. Pass quality level at G1 AQL 1.5			Meets Standard Requirements
Powder Free Residue	ASTM D6124-11 ASTM D6319-10	Result generated values ≤ 2 mg of residual powder per glove.			Meets Standard Requirements
Biocompatibility	Dermal Sensitization (as ISO 10993-10:2010)	Magnusson &Kligman Scale is '0'. Under the conditions of the study, the device is not a sensitizer.			Meets Standard Requirements
	Primary Skin Irritation Test (as ISO 10993-10:2010)	Primary Irritation Index for Erythema and Edema is '0'. Under the conditions of the study, the device is not an irritant.			Meets Standard Requirements

8.0 Substantial Equivalent Based on Assessment of Non-Clinical Performance Data

Powder Free Nitrile Patient Examination Glove, Black Colored, Non-Sterile have been tested against the applicable ASTM standards listed above, and meet the requirements set forth in those standards.

There is no difference between the Subject Device and the Predicate Device with respect to performance standard and technological characteristics.

9.0 Substantial Equivalent Based on Assessment of Clinical Performance Data

Clinical data was not needed.

10.0 Conclusion

The Substantial Equivalent Comparison Table below outlines the similarity, and/or differences between the subject device and the predicate device for the substantial equivalent determination.

As such, this device is substantially equivalent to predicate device.

It can be concluded that the Powder Free Nitrile Patient Examination Glove, Black Colored, Non-Sterile, is substantially equivalent to the predicate device identified in this 510(k) summary.

Substantial Equivalent Comparison Table

Characteristics	Subject Device	Predicate Device	Comments
Identification	K143131 Powder Free Nitrile Patient Examination Glove, Black Colored, Non-Sterile	K121529 Black Powder Free Nitrile Exam Glove	N/A
Device Classification Name/ Regulation Number	Patient Examination Glove/ 21 CFR Part 880.6250	Patient Examination Glove/ 21 CFR Part 880.6250	Substantially Equivalent
Product Code	80 LZA	80 LZA	Substantially Equivalent
Intended Use	Intended for medical and dental purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.	Intended for medical and dental purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.	Substantially Equivalent
Indications for Use	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.	The Examination Glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.	Substantially Equivalent
Materials	Nitrile	Nitrile	Substantially Equivalent
Color	Black	Black	Substantially Equivalent
Design	Ambidextrous, in different sizes per ASTM D6319 dimension requirement.	Ambidextrous, in different sizes per ASTM D6319 dimension requirement.	Substantially Equivalent
Performance I. Sterility II. Freedom from holes III. Dimension IV. Physical Properties V. Powder Free Residue	 Not Applicable (Non-Sterile) Passes at AQL 1.5 Meets ASTM D6319 Meets ASTM D6319 Meets ≤ 2 mg/glove	 Not Applicable (Non-Sterile) Passes at AQL 1.5 Meets ASTM D6319 Meets ASTM D6319 Meets ≤ 2 mg/glove	 Substantially Equivalent Substantially Equivalent Substantially Equivalent Substantially Equivalent Substantially Equivalent

Characteristics	Subject Device	Predicate Device	Comments
Single Use	Yes	Yes	Substantially Equivalent
Biocompatibility Test	Under the conditions of the study, the device is not a sensitizer or an irritant.	Passes i. Primary Skin Irritation Test – Gloves are non-irritating ii. Dermal Sensitization Test – Gloves do not display any potential for sensitization	Substantially Equivalent
Packaging	Packed in Dispenser Boxes	Packed in Dispenser Boxes	Substantially Equivalent
Labeling Features	- Non-sterile - Powder Free - Examination Gloves - Ambidextrous, by Size - Single Use Only - Device Color: Black - Manufactured for: - Lot Number: - Quantity by Weight - Made in Malaysia	- Non-sterile - Powder Free - Examination Gloves - Ambidextrous, by Size - Single Use Only - Device Color: Black - Manufactured for: - Lot Number: - Quantity by Weight - Made in Malaysia	Substantially Equivalent